REMARKS

In the Office Action dated April 14, 2005, claim 43 was withdrawn from consideration as being directed to a non-elected invention. Claim 42 was rejected under 35 U.S.C. § 101 because the claimed invention is said to be directed to non-statutory subject matter. Claims 3, 5, 6, 24-27 and 42 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,015,253 to MacGregor as evidenced by U.S. Patent No. 5,579,767 to Prince. Claim 42 was rejected under 35 U.S.C. § 102(b) as being anticipated by Caro (WO 95/09585). Claims 3, 5, 6, 24-30 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro in view of U.S. Patent No. 5,679,971 to Fischell et al. (Fischell). Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro and Fischell and in further view of U.S. Patent No. 5,104,404 to Wolf. For the reasons outlined in detail below, it is respectfully submitted that the pending claims patentably define over the cited art.

The Examiner is thanked for the courtesy of providing an interview to applicant's attorney on July 20, 2005. During the interview, a proposed amendment was discussed. Also discussed was the prior art to Caro and MacGregor. Moreover, applicant's attorney discussed the natural shape of blood vessels and how the blood flow in them is commonly swirling in nature. This provides a relatively uniform distribution of wall shear (see the instant specification, page 12, lines 18-21).

During the interview, newly submitted independent claim 44 was discussed. This claim recites a stent comprising a pre-shaped flexible supporting portion which supports an interior wall of the vessel and imposes a shape thereon. The supporting portion comprises a hollow tube including a wall and a plurality of openings located in the wall of the tube so that the interior wall of the vessel is exposed, via the openings, to fluid flow along the vessel. The hollow tube is at least partially helical in shape so that a swirling fluid flow is induced within the vessel.

As noted in the instant application, conventional stents are effectively straight cylinders. But, arteries curve three dimensionally (see the instant specification, page 10, lines 7-12). As a result, there is the problem of stent induced distortion of the geometry and flow field in arteries (see page 10, lines 26-28). In other words, the geometry of an artery, which is naturally curved in three dimensions, is altered by the insertion of a stent. This restricts the ability of the artery to maintain its curvature (see

the instant specification, page 11, lines 4-7). When the artery is unable to maintain its curvature, a uniform distribution of wall shear in the flowing blood is no longer achieved. This is disadvantageous because atherosclerosis appears to develop preferentially at locations in arteries where the wall shear is on average low and/or there are large oscillations of wall shear (see the instant specification, page 11, lines 18-21).

Typical of the prior art in this regard is the applied MacGregor reference. This patent discloses a stent that may be bent to the shape of the vessel in which it is positioned (see MacGregor, column 1, lines 60-62). In other words, the MacGregor stent 21 conforms to the vessel passageways (see column 6, lines 34-36). In contrast, the present invention pertains to a pre-shaped flexible supporting portion which imposes a shape on the vessel which it supports. The supporting portion comprises a hollow tube which is at least partially helical in shape so as to induce a swirling fluid flow within the vessel.

The non-planar, at least partially helical shape of a stent according to claim 44 is designed to induce swirl flow in the vessel. By providing openings in the walls of the stent so that the vessel wall interior is exposed to the swirl flow via the openings, the vessel wall experiences relatively high wall shear stress. Further, the vessel wall can experience a relatively uniform distribution of wall shear as mentioned. The benefits of having uniform wall shear and avoiding low wall shear are explained in the instant specification on page 11. For example, it is noted that the local flow pattern in blood vessels, including wall shear, markedly influences their biology and, it appears, the development of vascular disease (see the instant specification, page 11, lines 15-17). Thus, the cells of a vessel wall benefit from being subjected to shear stress, which helps to keep them healthy. Such mechanical stress is generated by near wall fluid flows in the vessel. By using a stent which induces swirl flow, in accordance with the present invention, a relatively uniform distribution of wall shear is obtained. This avoids or minimizes low wall shear regions in the vessel, at least in the area of the stent.

In contrast, MacGregor teaches away from the idea of the stent imposing a shape on a vessel. Rather, MacGregor teaches that the stent should itself adopt the shape of the vessel. There is no teaching or disclosure of a stent as recited in claim 44 in MacGregor or, indeed, in any of the remaining cited art. Accordingly, it is respectfully submitted that claim 44 patentably defines over the prior art.

New dependent claim 45 further recites a sensor operatively connected to the hollow tube, the sensor being adapted to transmit a signal responsive to one or more internal flow conditions. It is respectfully submitted that this claim also patentably defines over the art of record.

Applicant further submits herewith new dependent claim 46. This claim depends from claim 44 and recites that a rigidity of the hollow tube is reduced adjacent one end thereof. This subject matter is discussed in the instant specification on pages 5 and 6. It is there stated that the restraining action of the stent may be graduated by, for example, mechanically tapering the rigidity of the material. For example, at either end, the material may be removed or the rigidity reduced by cuttings (see the paragraph spanning pages 5 and 6). It is respectfully submitted that there is no teaching or disclosure of a stent having differential rigidity as recited in claim 46 in the cited prior art. Accordingly, claim 46 is also patentable over the prior art.

Independent claim 24 has been amended to recite a stent for insertion into a vessel, which stent internally supports an interior wall of that vessel and wherein when the stent is inserted into the vessel, the interior wall of the vessel is exposed via openings to fluid flow along the vessel. The supporting portion of the stent, when in the vessel, has a non-planar, at least partially helical shape. This imposes a non-planar, at least partially helical curve on the vessel, whereby fluid flow within the stent supported part of the vessel follows the non-planar curve to induce swirl flow. It is respectfully submitted that claim 24 patentably defines over MacGregor, even in view of Prince.

MacGregor has been previously discussed. Prince merely discloses a method for imaging abdominal aorta and aortic aneurisms. It neither teaches or discloses a stent comprising a supporting portion which has a non-planar, at least partially helical, shape so as to impose a non-planar, at least partially helical, curve on the vessel, thereby inducing swirl flow therein. Accordingly, claim 24 patentably defines over the applied combination of MacGregor and Prince.

Dependent claims 3, 5, 6 and 25-27 merely further patentably define the detailed subject matter of their parent claim. As such, these claims are also believed to be in condition for allowance over the applied combination of references, as well as the remainder of the cited art.

During the interview, the § 101 rejection of claim 42 was discussed. It was

agreed that the proposed amendments to claim 42 overcome the section 101 rejection of this claim.

Independent claim 42 was similarly rejected over MacGregor and Prince. Claim 42 recites a stent for insertion into an associated intact vessel so that the stent internally supports an interior wall of the vessel, the stent being of a shape and/or orientation which imposes a non-planar at least partially helical curve on the associated vessel. As mentioned previously, there is no teaching or disclosure of such a stent, even in the applied combination of MacGregor and Prince. Accordingly, claim 42 is also in condition for allowance over the applied combination of references, as well as the remainder of the cited art.

Claim 42 was also rejected as being anticipated by Caro. Caro pertains to a vascular prosthesis, as is evident from its title. While it is true that Caro mentions that one could, in addition to the prosthesis disclosed therein, use a stent internally, externally or integral to the wall of the Caro tubing, the tubing of the prosthesis must at all times be present. The Caro prosthesis is meant to replace a certain portion of a blood vessel. In contrast, the present invention relates to a stent for insertion into an associated intact vessel. The claimed invention does not pertain to the replacement of the vessel with a prosthesis, as in Caro. Rather, the stent recited in claim 42 internally supports an interior wall of the associated, intact, vessel. Accordingly, claim 42 patentably defines over Caro.

Claims 3, 5, 6, 24-30 and 42 were rejected under 35 U.S.C. § 103 as being unpatentable over Caro in view of Fischell. As mentioned with regard to claim 42, the teaching of Caro is the replacement of a blood vessel with a vascular prosthesis. In contrast, claim 24 recites a stent which internally supports a part of an intact vessel. The stent comprises a hollow tube with openings, so that when the stent is inserted into the vessel, the interior wall thereof is exposed via the openings to fluid flow. Such fluid flow allows the desired relatively uniform distribution of wall shear along the vessel wall, which appears to retard the development of atherosclerosis. Accordingly, claim 24 patentably defines over the combination of Caro and Fischell.

Fischell pertains to a multi cell stent. As with MacGregor, Fischell appears to disclose a stent design in which the stent can be bent to the shape of the vessel in which it is positioned, rather than inducing a non-planar at least partially helical shape

on the intact vessel, so as to induce a swirl flow within the blood or other fluid flowing in the vessel. It is noted that the teaching of Fischell is to a stent having at least two different types of cells. A first type of cell is intended to provide maximum radial rigidity after stent deployment. A second type of cell is designed to provide increased longitudinal flexibility, prior to stent deployment (see Fischell, column 1, lines 29-34).

It is contended in the Office Action that if the prosthesis of Caro was stented with the stent of Fischell and inserted into a blood vessel, then the openings of the stent would be "open to the extent required" so that the interior of the vessel part is not fully shielded. However, claim 24 requires that the openings of the supporting portion allow the interior wall of the vessel to be exposed to fluid flow along the vessel. Even if the Caro hollow tubing were modified by using a Fischell stent to provide structural support for the Caro prosthesis, the resulting stented tubing would not have openings which expose an intact vessel interior wall to fluid flow along the vessel. That is because Caro teaches a prosthesis and not a stent. With Caro, no vessel remains as the prosthesis replaces the vessel.

Accordingly, even the combination of Caro and Fischell neither teaches nor discloses the subject matter recited in claim 24.

Dependent claims 3, 5, 6 and 25-30 merely further patentably define the detailed subject matter of their parent claim or each other. As such, these claims are also believed to be in condition for allowance over the applied combination of Caro and Fischell.

Claim 31 was rejected as being unpatentable over Caro and Fischell in further view of Wolf. Wolf was merely used for its teaching of links which are coil shaped. However, even the applied three way combination of Caro, Fischell and Wolf, neither teaches nor discloses a stent having a supporting portion with a non-planar, at least partially helical shape, so as to impose a non-planar, at least partially helical curve on the vessel in which the stent is placed, thereby inducing a swirl flow within the stented part of the vessel. Accordingly, claim 31 is patentable over the applied three way combination, as well as the remainder of the cited art.

Dependent claims 12-16 were rejected under 35 U.S.C. § 103 as being unpatentable over Caro and Fischell in further view of Schwartz. Schwartz was merely used for its teaching of a monitoring device. However, even the applied three way

combination neither teaches nor discloses a stent having a supporting portion with a non-planar, at least partially helical shape which imposes a non-planar, at least partially helical curve on the stent supported part of the vessel, so as to induce swirl flow. Accordingly, claims 12-16 patentably define over the applied three way combination of references, as well as the remainder of the cited art.

Finally, independent claim 42 was rejected over Caro in view of Fischell. It is respectfully submitted that claim 42 also patentably defines over the applied combination of Caro and Fischell. Claim 42 recites a stent internally supporting an interior wall of an associated intact vessel part so as to impose a non-planar, at least partially helical curve on the associated vessel, whereby fluid flow within the stent supported part of the associated vessel follows a non-planar curve to induce swirl flow. It is respectfully submitted that claim 42 patentably defines over the applied combination of references, as well as the remainder of the cited art.

In view of the foregoing, it is respectfully submitted that all of the pending claims are now in condition for allowance over the art of record.

Respectfully submitted,

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July 27, 2005
Date

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CERTIFICATE OF MAILING

Under 37 C.F.R. § 1.8, I certify that this Amendment is being

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